

Application No. 09/475,721

B4  
Sub C7  
15. (Amended) The medical device of claim 10 wherein the medical device comprises a heart valve prosthesis and the composite component comprises leaflets.

16. ~~The medical device of claim 10 wherein the composite can be bent about 180 degrees without extending the material beyond its elastic limit.~~

B5  
Sub C5  
17. ~~(Amended) The medical device of claim 10 wherein the composite can be bent about 180 degrees with a radius of curvature of about the thickness of the composite without extending the material beyond its elastic limit.~~

18. The medical device of claim 10 wherein the composite can be bent about 60 degrees for about 40 million cycles without significant structural failure.

19. The medical device of claim 10 wherein the composite can be bent about 60 degrees for about 400 million cycles without significant structural failure.

20. The medical device of claim 10 wherein the composite further comprises a diamond-like carbon coating over at least a portion of the polymer.

B6  
Sub C7  
Please add new claim 21 as follows:

(New) The medical device of claim 1 wherein the polymer is crosslinked.

#### REMARKS

Claims 1-3 and 5-21 are pending. By this Amendment, claim 4 is canceled without prejudice, and claims 1, 5, 9, 10, 15 and 17 are amended. New claim 21 is added. Claim 9 was amended for clarity, and claims 5, 10, 15 and 17 were amended for minor grammatical changes. There is no intention of changing the scope of claims 5, 9, 10, 15 and 17. Claim 1 has been amended to more particularly point out Applicants' claimed invention. The amendment of claim 1 is supported by the specification, for example, at page 18, lines 31-33. New claim 21 is

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supported by the specification, for example, at page 21, lines 16-28. No new matter is introduced by the amendments or by the new claim.

All of the pending claims stand rejected. Applicants respectfully request reconsideration of the rejections based on the following remarks.

Rejections Under 35 U.S.C. §112, Second Paragraph

The Examiner rejected claims 1-20 under 35 U.S.C. §112, second paragraph as being indefinite. The Examiner cited several specific issues regarding the various claims. These specific issues are discussed in the order presented by the Examiner.

- 1) The Examiner indicated that claims 1-9 were indefinite for the recitation of the clause "the polymer forming a structure substantially different from the structure of the substrate." The Examiner indicated that this clause was indefinite unless defined by two different structures. Applicants believe that two different structures are recited, the structure of the substrate and the structure of the polymer covering at least a portion of the substrate. Applicants do not understand what is not clear about the claim language. Applicants request that the Examiner call the undersigned attorney to discuss the claim language if the Examiner still does not believe that the claim language is clear.
- 2) The Examiner asserted that claims 3 [4?] and 10-20 were indefinite based on the phrase "can be bent." In particular, the Examiner indicated that recitation of an intended use of the claimed invention must result in a structural difference. With all due respect, the recitation of "can be bent" indicates nothing about the intended use of the composite. Specifically, the recitation of "can be bent" relates to a functional characteristic of the material. Specification of functional characteristics is an accepted approach for describing materials in claims, see MPEP 2173.05(g). **The claims do not include any process limitations or use limitations.**
- 3) The Examiner indicated that claim 9 was unclear because it recited a slot or a hole. Applicants believe that the claim was clear as filed. A person of ordinary skill in the art

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would certainly understand the meaning and scope of the claim terms. However, to advance prosecution of the case, Applicants have amended claim 9 to recite structure forming a slot or a hole. As amended, Applicants believe that the claim is clear and definite.

4) The Examiner indicated that claims 10-20 were indefinite because the scope of "extending the material beyond its elastic limit" was unclear. According to Merriam Webster's Collegiate Dictionary, tenth edition, "elastic limit" is defined as "the greatest stress that an elastic solid can sustain without undergoing permanent deformation." In the specification at page 19, lines 12-15, it is stated that "the composite is not extended beyond its elastic limit, at which point the material would not return back to approximately its original position." This discussion in the specification is consistent with the dictionary definition. Thus, Applicants believe that there is only one possible interpretation on the claim language. Applicants believe that the claim language is clear and unambiguous based on both the ordinary dictionary definition of the claim language and the description in the specification.

5) The Examiner has indicated that claims 18 and 19 are unclear because it is unclear which component of the composite is bent and because the phrase "significant structural failure" is indefinite. First, the claims indicate that the composite is bent. The composite has two components, such that bending the composite involves the bending of both components of the composite since otherwise the composite is not being bent. The specification distinguishes flexibility of the composite from flexibility of the polymer, although the properties generally are related since the composite includes the polymer. With respect to the other issue in these claims, the Examiner has not indicated what is unclear about "significant structural failure." In any context, a person of ordinary skill in the art certainly can evaluate if a significant structural failure has occurred. Therefore, Applicants maintain that the claim terminology is clear.

6) The Examiner indicated that claim 20 was unclear because the meaning of diamond-like carbon was unclear. Diamond-like carbon is a well-known material that exists as a

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coating. For further background, Applicants refer to U.S. patent 5,725,573, which is incorporated into copending application 09/437,167, which is incorporated into the present application at page 23, lines 2-7. The '167 material further states the following:

Diamond-like carbon coatings yield an electron diffraction image with a halo pattern and a Raman vibrational spectrum with broad peaks indicative of inhomogeneous broadening due to an amorphous structure centered at frequencies of  $1580\text{ cm}^{-1}$  and  $1360\text{ cm}^{-1}$ . Typical ranges of selected properties of several forms of carbon materials at  $25^{\circ}\text{C}$  are presented in Table 1.

TABLE 1\*

{PRIVATE }Carbon Form	Density (g/cm <sup>3</sup> )	Young's modulus (GPa)	Hardness (kg/mm <sup>2</sup> )	Thermal Conductivity (W/mK)
DLC	1.6-2.8	45+	800-9000	100 - 1000
Pyrolytic Graphite, oriented	2.1-2.2	28-40	240-370	190-390 (ab directions) 1-3 (c direction)
Vitreous	1.5	35	340	4.6
Graphite	1.7-1.9	5-10	40-100	31 (lamp black) 159 (petrol. coke)
Diamond	3.5	910-1250	5000-10,000	600-1000 (Type Ia)

\* See Handbook of Carbon, Graphite, Diamond and Fullerenes: Properties, Processing and Application, by Hugh O. Pierson, Noyes Publication, Park Ridge, New Jersey, U.S.A. (1993), incorporated herein by reference.

Since diamond-like carbon is a well known material and described in the '167 application which is incorporated by reference into the present application, applicants believe that the claim is clear.

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Summary of Section 112 Issues

In view of the above comments, Applicants believe that all of the presently pending claims are clear and unambiguous. Applicants respectfully request the withdrawal of the rejection of claims 1-20 under 35 U.S.C. §112, second paragraph as being indefinite.

Rejection Under 35 U.S.C. §102

The Examiner rejected claims 1-17 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent 4,778,461 to Pietsch et al. (the Pietsch patent). Applicants have amended claim 1 to more particularly point out their claimed invention. Furthermore, Applicants have clarified the scope of claim 10 in the above discussion relating to Section 112 rejections. Applicants respectfully request reconsideration of the rejection over the Pietsch patent in view of the following comments.

With respect to claims 1-9, claim 1 has been amended to indicate that the polymer is rigid. In contrast, the Pietsch patent discloses flexible polymers. See, for example, column 1, lines 63-68 and column 2, lines 34-41. Since the Pietsch patent does not disclose rigid polymers, the Pietsch patent does not anticipate claims 1-9.

With respect to claims 10-17, the Pietsch patent does not disclose a composite that can be bent at least about 100 degrees without extending the material beyond its elastic limit. As clarified above in the discussion of the rejections under section 112, these claims refer to the bending of both components of the composite, the substrate and the polymer. Since the Pietsch patent does not disclose composites that can bend the specified amount, the Pietsch patent does not anticipate claims 10-17.

Based on the above discussion, the Pietsch patent does not anticipate any of Applicants' claimed inventions. Applicants respectfully request withdrawal of the rejection of claims 1-17 under 35 U.S.C. §102(b) as being anticipated by the Pietsch patent.

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Rejection Under 35 U.S.C. §103 Over Pietsch et al.

The Examiner rejected claims 18 and 19 under 35 U.S.C. §103(a) as being unpatentable over the Pietsch patent. The Examiner takes the position that since the Pietsch patent discloses high fatigue strength and other properties, the Pietsch patent suggests leaflets that can bend for 400 million cycles without significant structural failure. Applicants respectfully request reconsideration of the rejection over the Pietsch patent based on the following comments.

As clarified above, the claims refer to bending of the composites, i.e., inorganic substrate and polymer, and not just the bending of a component of the composite, such as the polymer. Therefore, the Examiner's position with respect to whether or not the Pietsch leaflets would be expected to bend 400 million cycles are not on point. Specifically, Applicants noted above that the Pietsch patent does not teach or suggest a **composite** that can bend 100 degrees without exceeding its elastic limit. Due to this deficiency in the Pietsch patent with respect to the present invention, the Pietsch patent does not render claims 18 and 19 obvious. Applicants respectfully request withdrawal of the rejection of claims 18 and 19 under 35 U.S.C. §103(a) as being unpatentable over the Pietsch patent.

Rejection Over Pietsch et al. and Sumitomo Electric Co. Abstract

The Examiner rejected claim 20 under 35 U.S.C. §103(a) as being unpatentable over the Pietsch patent, as applied to claims 18 and 19, in view of JP abstract 59192366 to Sumitomo Electric Co. (the Sumitomo abstract). The Examiner cited the Sumitomo abstract for disclosing diamond-like carbon on a heart valve prosthesis. Applicants respectfully request reconsideration of the rejection base on the combination of the Pietsch patent and the Sumitomo abstract based on the following comments.

As noted above, the Pietsch patent does not disclose a composite with an inorganic substrate and a polymer at least partly covering the substrate that can bend 100 degrees

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without extending past its elastic limit. The Sumitomo abstract similarly does not teach a composite of the present claim. Since neither of the cited references teach or suggest the claimed composites, the combined disclosures of the Pietsch patent and the Sumitomo abstract do not render the present invention obvious. Applicants respectfully request withdrawal of the rejection of claim 20 under 35 U.S.C. §103(a) as being unpatentable over the Pietsch patent, as applied to claims 18 and 19, in view of the Sumitomo abstract.

## CONCLUSIONS

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,



Peter S. Dardi, Ph.D.  
Registration No. 39,650

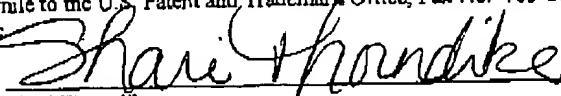
Customer No. 24113  
Patterson, Thuent, Skaar & Christensen, P.A.  
4800 IDS Center  
80 South 8th Street  
Minneapolis, Minnesota 55402-2100  
Telephone: (612) 349-5746

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I hereby certify that this paper is being transmitted by facsimile to the U.S. Patent and Trademark Office, Fax No. 703-872-9310 on the date shown below thereby constituting filing of same.

December 13, 2001  
Date

  
Shari Thorndike

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ATTACHMENT  
MARKED-UP AMENDMENTClaims As Amended

Claim 4 has been canceled without prejudice or disclaimer.

Claims 1, 5, 9, 10, 15 and 17 have been amended as follows:

1. (Amended) A medical device comprising a composite having an inorganic substrate and a polymer covering at least a portion of the substrate, the polymer forming a structure substantially different from the structure of the substrate and the polymer being rigid.
5. (Amended) The medical device of claim 1 wherein the polymer is selected from the group consisting of polyetheretherketones, polyacetals, polyamides, polypropylenes, polyurethanes, polytetrafluoroethylenes, polyester teraphthalates, polycarbonates, and polysulfones.
9. (Amended) The medical device of claim 1 wherein the polymer material has structure forming [forms] a slot, hole, pin, button, barb or anchor.
10. (Amended) A medical device comprising a flexible composite component comprising an inorganic substrate and a polymer member covering at least [over] a portion of the substrate, wherein the composite can be bent[,] at least[,] about 100 degrees without extending the material beyond its elastic limit.
15. (Amended) The medical device of claim 10 wherein the medical device comprises a heart valve prosthesis and the composite component comprises [comprising] leaflets.



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17. (Amended) The medical device of claim 10 wherein the composite can be bent about 180 degrees with a radius of curvature of about the thickness of the composite without extending the material beyond its elastic limit.

New claim 21 has been added as follows:

--21. (New) The medical device of claim 1 wherein the polymer is crosslinked.--